PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.:		10/621,972	Confirmation No.: 2230
Applicant	:	Ross S. Tsugita	
Filed	:	July 17, 2003	
TC/A.U.	:	3734	
Examiner	:	Blatt, Eric D.	
Title	:	FILTER FLUSH SYSTEM AND METHODS OF USE	
Docket No.	:	1001.1421103	
Customer No.	:	28075	

APPEAL BRIEF FILED UNDER 37 C.F.R. § 41.37

Mail Stop Appeal Brief - Patents
Assistant Commissioner for Patents
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Alexandria, VA 22313-1450

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By _____
JoAnn Lindman

Dear Sirs:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on March 15, 2010, and of the Notice of Panel Decision from Pre-Appeal Review dated mailed May 21, 2010. Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $540 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Boston Scientific Scimed, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One Scimed Place, Maple Grove, MN 55311-1566. An assignment from the inventor, Ross S. Tsugita, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 11541, Frame 0810. A Change of Name from SciMed Life Systems, Inc. to Boston Scientific Scimed, Inc. has been recorded at Reel 018505, Frame 0868.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 53-80 are pending in the application, of which claims 72-77 are withdrawn. Claims 1-52 have been canceled from the application.

Claim 63 stands finally rejected under 35 U.S.C. 112, first paragraph.

Claim 78 stands finally rejected under 35 U.S.C. 112, second paragraph.

Claims 53-58, 60-65, and 68-71 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gray et al., WO 99/22673, in view of Patel, U.S. Patent No. 4,832,028.

Claims 59, 66, 67, and 78-81 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gray et al., WO 99/22673, in view of Patel, U.S. Patent No. 4,832,028, as applied to claims 53 and 56, and further in view of Dubrul, U.S. Patent No. 6,258,115. (Note that there is no claim 81.)

Claims 53-71 and 78-80 of the application are currently being appealed.

IV. STATUS OF AMENDMENTS

Claims 78 has been amended subsequent the final rejection of October 14, 2009.

V. SUMMARY OF CLAIMED SUBJECT MATTER*

The invention is directed generally to a medical device for use in a body lumen, said device comprising first and second catheters; a guidewire having a filter coupled thereto which is slidably disposed in a lumen of the second catheter which in turn is slidably disposed within a lumen of the first catheter; an occlusive balloon coupled to the distal end region of the first catheter; and a stent disposed adjacent to the second catheter. The general operational sequence of an exemplary medical device is illustrated in Figures 4A-4C.

Turning now to independent claim 53, which is directed to a medical device for use in a body lumen, the device comprising: a first catheter shaft (see, for example, specification page 11, line 15 to page 13, line 5, page 15, lines 10-11, page 16, lines 9-14 and line 22 to page 17, line 1, page 17, lines 19-23, page 18, lines 2-5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30) having a proximal end (see, for example, specification page 6, line 4) region, a distal end region (see, for example, specification page 6, line 3, page 11, lines 15-17, Figs. 1B; reference numeral 31), and a fluid lumen (see, for example, specification page 11, lines 15-11, page 12, lines 18-19, page 15, lines 14-16, page 16, lines 9-13, page 17, line 8-10 and 19-21, page 18, lines 6-8 and 18-19) connecting the proximal end (see, for example, specification page 6, line 4) region and the distal end region (see, for example, specification page 6, line 3, page 11, lines 15-17, Figs. 1B; reference numeral 31); a second catheter shaft (see, for example, specification page 6, lines 10-19, page 7, lines 16-19, page 8, lines 15-20, page 9, lines1-3, lines 6-10 and lines 21-22, page 11, lines 18-22, page 12, lines 6-8 and 16-18, page 15, lines 14-20, page 16, lines 9-10, page 17, lines 8-21; Figs. 3B, 4B; reference numeral 50, 65) slidably disposed within the first catheter shaft (see, for example, specification page 11, line 15 to page 13, line 5, page 15, lines 10-11, page 16, lines 9-14 and line 22 to page 17, line 1, page 17, lines 19-23, page 18, lines 2-5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30); a guidewire (see, for example, specification page 5, line 22 to page 6, line 13, page 8, line 11 to page 9, line 4, page 11, lines 6-14 and line 18 to page 12, line 8, page 13, lines 2-7, page 15, lines 10-16, page 16, line 22 to page 17, line 10,

* The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting as support may be found throughout the specification and in many of the Figures.

page 18, lines 16-18; Figs. 1B, 2A-C, 3B-C, 5; reference numeral 10) slidably disposed in a lumen (see, for example, specification page 6, lines 12-13, page 7, lines 8-9) of the second catheter shaft (see, for example, specification page 6, lines 10-19, page 7, lines 16-19, page 8, lines 15-20, page 9, lines1-3, lines 6-10 and lines 21-22, page 11, lines 18-22, page 12, lines 6-8 and 16-18, page 15, lines 14-20, page 16, lines 9-10, page 17, lines 8-21; Figs. 3B, 4B; reference numeral 50, 65); a filter (see, for example, specification page 5, line 18 to page 6, line 3, page 6, line 22 to page 7, line 10, page 8, line 11 to page 9, line 9, page 11, lines 6-12 and line 22 to page 12, line 5 and line 12 to page 13, line 4, page 14, lines 10-11, page 15, lines 4-5 and line 23 to page 16, line 2 and lines 11-19, page 17, line 23 to page 18, line 5; Figs. 1A-B, 2A-C, 3C, 4A-C, 5; reference numeral 20) coupled to the guidewire (see, for example, specification page 5, line 22 to page 6, line 13, page 8, line 11 to page 9, line 4, page 11, lines 6-14 and line 18 to page 12, line 8, page 13, lines 2-7, page 15, lines 10-16, page 16, line 22 to page 17, line 10, page 18, lines 16-18; Figs. 1B, 2A-C, 3B-C, 5; reference numeral 10); a balloon (see, for example, specification page 6, lines 4-7, page 7, lines 11-12, page 8, lines 14-20, page 9, lines 4-5 and 10-13, page 11, line 15-18, page 12, lines 9-20, page 15, lines 22-23, page 16, lines 11-13, page 18, lines 6-21; Figs. 1B, 2A-C, 3A-C, 4A-C, 5; reference numeral 40) coupled to the distal end region (see, for example, specification page 6, line 3, page 11, lines 15-17, Figs. 1B; reference numeral 31) of the first catheter shaft (see, for example, specification page 11, line 15 to page 13, line 5, page 15, lines 10-11, page 16, lines 9-14 and line 22 to page 17, line 1, page 17, lines 19-23, page 18, lines 2-5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30); a stent (see, for example, specification page 6, lines 6-21, page 16, lines 3-8, page 17, line 8 to page 18, line 1; Figs. 4B-C; reference numeral 60) disposed adjacent the second catheter shaft (see, for example, specification page 6, lines 10-19, page 7, lines 16-19, page 8, lines 15-20, page 9, lines1-3, lines 6-10 and lines 21-22, page 11, lines 18-22, page 12, lines 6-8 and 16-18, page 15, lines 14-20, page 16, lines 9-10, page 17, lines 8-21; Figs. 3B, 4B; reference numeral 50, 65), wherein the balloon (see, for example, specification page 6, lines 4-7, page 7, lines 11-12, page 8, lines 14-20, page 9, lines 4-5 and 10-13, page 11, line 15-18, page 12, lines 9-20, page 15, lines 22-23, page 16, lines 11-13, page 18, lines 6-21; Figs. 1B, 2A-C, 3A-C, 4A-C, 5; reference numeral 40) and the first catheter shaft (see, for example,

specification page 11, line 15 to page 13, line 5, page 15, lines 10-11, page 16, lines 9-14 and line 22 to page 17, line 1, page 17, lines 19-23, page 18, lines 2-5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30) are configured to stop fluid outside of the first catheter shaft (see, for example, specification page 11, line 15 to page 13, line 5, page 15, lines 10-11, page 16, lines 9-14 and line 22 to page 17, line 1, page 17, lines 19-23, page 18, lines 2-5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30) proximal to the balloon (see, for example, specification page 6, lines 4-7, page 7, lines 11-12, page 8, lines 14-20, page 9, lines 4-5 and 10-13, page 11, line 15-18, page 12, lines 9-20, page 15, lines 22-23, page 16, lines 11-13, page 18, lines 6-21; Figs. 1B, 2A-C, 3A-C, 4A-C, 5; reference numeral 40) from flowing distally past the distal region (see, for example, specification page 6, line 3, page 11, lines 15-17, Figs. 1B; reference numeral 31) of the shaft (see, for example, specification page 11, line 15 to page 13, line 5, page 15, lines 10-11, page 16, lines 9-14 and line 22 to page 17, line 1, page 17, lines 19-23, page 18, lines 2-5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30) when the balloon (see, for example, specification page 6, lines 4-7, page 7, lines 11-12, page 8, lines 14-20, page 9, lines 4-5 and 10-13, page 11, line 15-18, page 12, lines 9-20, page 15, lines 22-23, page 16, lines 11-13, page 18, lines 6-21; Figs. 1B, 2A-C, 3A-C, 4A-C, 5; reference numeral 40) is expanded; wherein the stent (see, for example, specification page 6, lines 6-21, page 16, lines 3-8, page 17, line 8 to page 18, line 1; Figs. 4B-C; reference numeral 60) is self-expanding and configured to be deployed from a position between the distal end (see, for example, specification page 6, line 3, page 11, lines 15-17, Figs. 1B; reference numeral 31) of the first catheter shaft (see, for example, specification page 6, line 3, page 11, line 15 to page 13, line 5, page 15, lines 10-11, page 16, lines 9-14 and line 22 to page 17, line 1, page 17, lines 19-23, page 18, lines 2-5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30) and the filter (see, for example, specification page 5, line 18 to page 6, line 3, page 6, line 22 to page 7, line 10, page 8, line 11 to page 9, line 9, page 11, lines 6-12 and line 22 to page 12, line 5 and line 12 to page 13, line 4, page 14, lines 10-11, page 15, lines 4-5 and line 23 to page 16, line 2 and lines 11-19, page 17, line 23 to page 18, line 5; Figs. 1A-B, 2A-C, 3C, 4A-C, 5; reference numeral 20); and wherein the first catheter shaft (see, for example, specification page 11, line 15 to page 13, line 5, page 15, lines 10-11, page 16, lines 9-14 and line 22

to page 17, line 1, page 17, lines 19-23, page 18, lines 2-5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30) defines a perfusion lumen (see, for example, specification page 6, lines 12-13, page 7, lines 8-9, page 11, lines 15-17, Figs. 1B; reference numeral 31) configured for the passage of perfusing fluid supplied at the proximal end region therethrough so as to flush embolic debris into the filter (see, for example, specification page 5, line 18 to page 6, line 3, page 6, line 22 to page 7, line 10, page 8, line 11 to page 9, line 9, page 11, lines 6-12 and line 22 to page 12, line 5 and line 12 to page 13, line 4, page 14, lines 10-11, page 15, lines 4-5 and line 23 to page 16, line 2 and lines 11-19, page 17, line 23 to page 18, line 5; Figs. 1A-B, 2A-C, 3C, 4A-C, 5; reference numeral 20).

Turning now to independent claim 68, which is directed to a medical device for use in a body lumen, the device comprising: an outer catheter shaft (see, for example, specification page 11, line 15 to page 13, line 5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30) having a proximal end (see, for example, specification page 6, line 4) and a distal end (see, for example, specification page 6, line 3, page 11, lines 15-17, Figs. 1B; reference numeral 31); an inner catheter shaft (see, for example, specification page 6, lines 10-19, page 7, lines 16-19, page 8, lines 15-20, page 9, lines1-3, lines 6-10 and lines 21-22, page 11, lines 18-22, page 12, lines 6-8 and 16-18, page 15, lines 14-20, page 16, lines 9-10, page 17, lines 8-21; Figs. 3B, 4B; reference numeral 50, 65) slidably disposed in the outer catheter shaft (see, for example, specification page 11, line 15 to page 13, line 5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30), said inner catheter shaft (see, for example, specification page 6, lines 10-19, page 7, lines 16-19, page 8, lines 15-20, page 9, lines1-3, lines 6-10 and lines 21-22, page 11, lines 18-22, page 12, lines 6-8 and 16-18, page 15, lines 14-20, page 16, lines 9-10, page 17, lines 8-21; Figs. 3B, 4B; reference numeral 50, 65) having a proximal end and a distal end; an elongate guidewire (see, for example, specification page 5, line 22 to page 6, line 13, page 8, line 11 to page 9, line 4, page 11, lines 6-14 and line 18 to page 12, line 8, page 13, lines 2-7, page 15, lines 10-16, page 16, line 22 to page 17, line 10, page 18, lines 16-18; Figs. 1B, 2A-C, 3B-C, 5; reference numeral 10) slidably disposed in the inner catheter shaft (see, for example, specification page 6, lines 10-19, page 7, lines 16-19,

page 8, lines 15-20, page 9, lines1-3, lines 6-10 and lines 21-22, page 11, lines 18-22, page 12, lines 6-8 and 16-18, page 15, lines 14-20, page 16, lines 9-10, page 17, lines 8-21; Figs. 3B, 4B; reference numeral 50, 65); a filter (see, for example, specification page 5, line 18 to page 6, line 3, page 6, line 22 to page 7, line 10, page 8, line 11 to page 9, line 9, page 11, lines 6-12 and line 22 to page 12, line 5 and line 12 to page 13, line 4, page 14, lines 10-11, page 15, lines 4-5 and line 23 to page 16, line 2 and lines 11-19, page 17, line 23 to page 18, line 5; Figs. 1A-B, 2A-C, 3C, 4A-C, 5; reference numeral 20) coupled to the guidewire (see, for example, specification page 5, line 22 to page 6, line 13, page 8, line 11 to page 9, line 4, page 11, lines 6-14 and line 18 to page 12, line 8, page 13, lines 2-7, page 15, lines 10-16, page 16, line 22 to page 17, line 10, page 18, lines 16-18; Figs. 1B, 2A-C, 3B-C, 5; reference numeral 10); a balloon (see, for example, specification page 6, lines 4-7, page 7, lines 11-12, page 8, lines 14-20, page 9, lines 4-5 and 10-13, page 11, line 15-18, page 12, lines 9-20, page 15, lines 22-23, page 16, lines 11-13, page 18, lines 6-21; Figs. 1B, 2A-C, 3A-C, 4A-C, 5; reference numeral 40) coupled to the outer catheter shaft (see, for example, specification page 11, line 15 to page 13, line 5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30); and a self-expanding stent (see, for example, specification page 6, lines 6-21, page 16, lines 3-8, page 17, line 8 to page 18, line 1; Figs. 4B-C; reference numeral 60) coupled to the inner catheter shaft (see, for example, specification page 6, lines 10-19, page 7, lines 16-19, page 8, lines 15-20, page 9, lines1-3, lines 6-10 and lines 21-22, page 11, lines 18-22, page 12, lines 6-8 and 16-18, page 15, lines 14-20, page 16, lines 9-10, page 17, lines 8-21; Figs. 3B, 4B; reference numeral 50, 65), wherein the balloon (see, for example, specification page 6, lines 4-7, page 7, lines 11-12, page 8, lines 14-20, page 9, lines 4-5 and 10-13, page 11, line 15-18, page 12, lines 9-20, page 15, lines 22-23, page 16, lines 11-13, page 18, lines 6-21; Figs. 1B, 2A-C, 3A-C, 4A-C, 5; reference numeral 40) and the outer catheter shaft (see, for example, specification page 11, line 15 to page 13, line 5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30) are configured to stop fluid from outside the outer catheter shaft (see, for example, specification page 11, line 15 to page 13, line 5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30) proximal to the balloon (see, for example, specification page 6, lines 4-7, page 7, lines 11-12, page 8, lines 14-20, page 9, lines 4-5 and 10-13, page 11, line 15-18, page 12,

lines 9-20, page 15, lines 22-23, page 16, lines 11-13, page 18, lines 6-21; Figs. 1B, 2A-C, 3A-C, 4A-C, 5; reference numeral 40) from flowing distally past the balloon (see, for example, specification page 6, lines 4-7, page 7, lines 11-12, page 8, lines 14-20, page 9, lines 4-5 and 10-13, page 11, line 15-18, page 12, lines 9-20, page 15, lines 22-23, page 16, lines 11-13, page 18, lines 6-21; Figs. 1B, 2A-C, 3A-C, 4A-C, 5; reference numeral 40) when the balloon (see, for example, specification page 6, lines 4-7, page 7, lines 11-12, page 8, lines 14-20, page 9, lines 4-5 and 10-13, page 11, line 15-18, page 12, lines 9-20, page 15, lines 22-23, page 16, lines 11-13, page 18, lines 6-21; Figs. 1B, 2A-C, 3A-C, 4A-C, 5; reference numeral 40) is expanded; and wherein at least one of the inner (see, for example, specification page 6, lines 10-19, page 7, lines 16-19, page 8, lines 15-20, page 9, lines1-3, lines 6-10 and lines 21-22, page 11, lines 18-22, page 12, lines 6-8 and 16-18, page 15, lines 14-20, page 16, lines 9-10, page 17, lines 8-21; Figs. 3B, 4B; reference numeral 50, 65) or outer catheter (see, for example, specification page 11, line 15 to page 13, line 5; Figs. 1B, 2A-C, 3A, 3C, 4A, 4C, and 5; reference numeral 30) shafts define a perfusion lumen (see, for example, specification page 6, lines 12-13, page 7, lines 8-9, page 11, lines 15-17, Figs. 1B; reference numeral 31) therein that is configured for perfusing fluid therethrough from an infusion port proximate the proximal end (see, for example, specification page 6, line 4) of the shaft so as to flush embolic debris into the filter (see, for example, specification page 5, line 18 to page 6, line 3, page 6, line 22 to page 7, line 10, page 8, line 11 to page 9, line 9, page 11, lines 6-12 and line 22 to page 12, line 5 and line 12 to page 13, line 4, page 14, lines 10-11, page 15, lines 4-5 and line 23 to page 16, line 2 and lines 11-19, page 17, line 23 to page 18, line 5; Figs. 1A-B, 2A-C, 3C, 4A-C, 5; reference numeral 20).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether the rejection of claim 63 under 35 U.S.C. 112, first paragraph is proper.

2. Whether the amendment of claim 78 overcomes the final rejection under 35 U.S.C. 112, second paragraph.

3. Whether claims 53-58, 60-65, and 68-71 are patentable under 35 U.S.C. §103(a) over Gray et al., WO 99/22673, in view of Patel, U.S. Patent No. 4,832,028?

4. Whether claims 59, 66, 67, and 78-80 are patentable under 35 U.S.C. §103(a) over Gray et al., WO 99/22673, in view of Patel, U.S. Patent No. 4,832,028, as applied to claims 53 and 56, and further in view of Dubrul, U.S. Patent No. 6,258,115.

VII. ARGUMENT

A. THE REJECTION CLAIM 63 UNDER 35 U.S.C. 112, FIRST PARAGRAPH IS IMPROPER.

It was asserted that the specification does not describe the first catheter includes an infusion port within the proximal end region in such a way as to reasonably convey to one of skill in the art that the inventor had possession of the claimed invention. Applicant respectfully disagrees. Claim 53, from which claim 63 depends, describes "a first catheter shaft having a proximal end region, a distal end region, and a fluid lumen connecting the proximal end region and the distal end region. The Abstract states:

> "Fluid medium or blood can be infused through the lumen of the guiding catheter to flush embolic material or mobile plaque generated during the endovascular procedures toward the expanded filter deployed downstream from the region of interest."

Similarly, at page 8, lines 20-22:

> "The catheter may then be withdrawn or left in place, and fluid or blood is infused through the lumen of the guiding catheter to flush embolic debris into the expanded filter."

and at page 16, lines 11-13

> "Before or after deflation of balloon 40, fluid or blood can be infused through lumen 33 and port 35 to flush embolic material into filter 20."

and still further as described at page 7, lines 11-15:

> In still another embodiment, the guiding catheter includes an infusion port proximal to the occlusion balloon. The port communicates with an infusion lumen in the catheter and is adapted for infusion of fluid or pharmaceutical agents. Using the infusion port, the dosage of pharmaceutical agent required to achieve local effect can be reduced compared to administration by systemic route.

the catheter has at least one lumen 33 communicating with a proximal end and thus an

regards as the invention indicating insufficient antecedent basis for the limitation "the

"the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded" (claims 53 and 68).

The stabilized catheter assembly of Patel serves to lock the tip of the catheter in the ostium where it resists reactionary forces which otherwise may cause the guiding catheter to slip out of the coronary opening. The catheter assembly is characterized as follows:

"The guiding catheter has an inflatable balloon near the tip for engaging the inner surface of the coronary lumen when inflated. The guiding catheter also has a side hole for perfusion of blood through the guiding catheter while the balloon on the guiding catheter is inflated." (Abstract)

"The balloon engages the inner surface of the coronary artery, and stabilizes the guiding catheter. The dilating catheter is then passed through the guiding catheter and through the stenotic lesion, without forcing the guiding catheter out of the coronary lumen.

Side holes in the guiding catheter allow blood to bypass the inflated balloon on the guiding catheter. Otherwise, the inflated balloon would obstruct the flow of blood to the coronary artery." (Col. 1, lines 47-56.)

"Blood is perfused through the side hole 27 and the tip 21 of the guiding catheter 11 into the main coronary 19. Blood flow is thus not restricted by the inflated balloon 25 on the guiding catheter 11." (Col. 2, lines 65-68.)

"This holds the guiding catheter 11 in place, allowing the dilating catheter 29 to be passed through tight stenotic lesions 31 more easily. Further, although the balloon 25 on the guiding catheter 11 contacts the inner surface of the coronary artery 19, blood flow is not restricted. Blood is perfused through the side hole 27 in the guiding catheter 11." (Col. 3, lines 20-27.)

"The side hole 27 passes through the guiding catheter 11 to allow blood to flow from the aorta 13, through the side hole 27, and out the tip 21 of the guiding catheter 11." (Column 2, lines 20-23.)

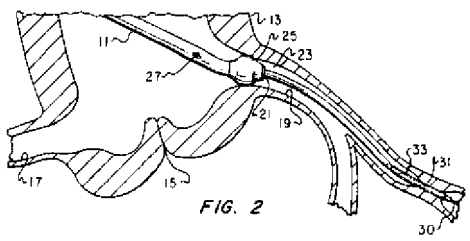

FIG. 2

Thus Patel explicitly and emphatically discloses that blood flows from the aorta, which is from outside the catheter 11, through the side hole 27 and out the (distal) tip 21 of the guiding catheter 11 and into the ostium 23 of the coronary artery 19.

The Examiner clearly errs in asserting in the Final Office Action, "The Examiner first notes that the language requires only that the balloon and first catheter shaft are configured to stop fluid outside of the first catheter shaft from flowing distally past the distal region of the shaft. Blood that flows into port 27 is not outside of the first catheter shaft." Appellant asks, "Where is the source of blood that flows into the port 27and out of tip 21 if not in the aorta 13 and outside of the guiding catheter 11?" Appellant further notes that the claim language indicates that blood which initially is outside of the catheter is to be stopped from flowing past the tip without specifying the path which the stopped flow might otherwise take. The Examiner has persisted in an erroneous belief that the claim language specifies that the flow to be stopped by the balloon/catheter combination must remain outside of the balloon/catheter combination. Instead, the claim specifies a source location, "outside of the first catheter shaft proximal to the balloon", and a location for a flow to be stopped, "distally past the distal region of the shaft", and a condition under which the flow from the first location to the second location is to be prevented, namely "when the balloon is expanded".

Although this argument is believed to be fully persuasive, it should also be noted that Patel does not teach or otherwise disclose that the holding/locking balloon is in any way occlusive. The only function attributed to the balloon 25 of Patel is that of holding/locking the catheter within the ostium of the coronary artery. Although the holding balloon of Patel may somewhat obstruct blood flow, it does not appear to stop the flow and stopping the bypass flow would be counter to the explicit teachings of Patel that flow from the aorta into the coronary artery distally past the tip is to be maintained. Thus Patel does not disclose, in a manner which would be so recognized by persons of ordinary skill, that blood from the aorta necessarily would be prevented from flowing past the balloon along the outside of the catheter/balloon when the balloon is inflated. Thus Patel does not appear to teach or otherwise disclose stopping fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded, as recited in independent claims 53 and 68.

The Examiner has explicitly acknowledged: "Gray fails to disclose a first shaft (claim 53) or outer catheter (claim 68) with a balloon coupled thereto" and relies upon Patel to provide the missing element of the independent claims. Gray does not advance a filter and/or dilating catheter through a first or outer guiding catheter and over a guidewire as taught by Patel and thus would not appear to encounter the potential problem of "forcing the guiding catheter out of the coronary lumen" In the absence of the reactive forces which may give rise to this ejection problem, or even of a guiding catheter upon which the forces might act, Gray does not have a problem which would be solved by the Examiner's proposed combination of Gray and Patel. The motivation for the combination of Gray and Patel, which has been proposed by the Examiner, does not exist until the outer catheter of Patel is added, unnecessarily, to the filter guidewire of Gray.

As discussed above, Patel does not provide a balloon which necessarily is capable of stopping blood flow from a point outside of the catheter and proximal of the balloon to a point distally past the distal region of the shaft and does teach that it would be undesirable to do so. Patel teaches only blood within the aorta as a source of bypass blood flow to perfuse tissue downstream from the balloon and so one of ordinary skill in the art would appreciate that blood must either bypass the balloon directly or bypass it by means of entering hole 27. Gray does not occlude the vessel and so the issue does not arise. The current invention supplies blood through the lumen 33 from a proximal end port and thus solves the problem of perfusion by a different means. Thus Gray in view of Patel does not teach all the claim limitations, as is required to establish a *prima facie* case of obviousness.

In attempting to rebut Appellant's arguments, the Examiner has employed a hypothetical division of the catheter of Patel in which that portion of the catheter of Patel which lies distal of the balloon of Patel is construed to be "a distal end region" and the entirety of the catheter proximal of the balloon is construed to be "a proximal end region" with the assertion that the side hole 27, located within the aorta and adjacent to the balloon, is located in a proximal end region thereby ignoring the term "end" as that term would be interpreted by one of ordinary skill in the art.

> The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). 37 CFR 1.75(d)(1).
>
> Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998) ("Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings.")

Appellant submits that one of ordinary skill in the art would not construe side hole 27 located within the aorta and adjacent to distal balloon 25 in the disclosure of Patel to be located in "a proximal end region" of said catheter for at least the reason that the proximal end region lies near the proximal end and outside of the body and further submits that the Examiner's interpretation is particularly at odds with the interpretation of the claims by one of ordinary skill in the art in light of the specification and drawings of the pending application which disclose and illustrate (Fig. 1B, 2A-C, 3A-C, and 4A-C) as a port at the proximal end of the catheter as shown. Absent disclosure to the contrary, a proximal end region must lie in the vicinity of the proximal end and would be expected to be separated from a distal end region to which the balloon is coupled by an intermediate region of the an angioplasty catheter of the invention, in this case, a length of at least about 100 cm for a catheter to be introduced into the aorta through the femoral artery as taught by Patel at col. 1, lines 17-19. It is only the Examiner's assertion, without support in the disclosure of Patel or other indication, that one of ordinary skill in the art would adopt such an interpretation, that distal port 27 of Patel, located no more than a few centimeters from the distal end of catheter 11, may be considered to be located within "a proximal end region", which allows a port in the distal region of the catheter of Patel to be considered to be located anywhere but near the distal end of the catheter in question.

The Examiner erroneously has attempted to rely upon the existence of infusion port 70 in an alternate embodiment illustrated in Fig. 5 of the pending application which does allow fluid intake and blood to flow from the proximal side of the occlusion balloon and exit distal port 35 of the catheter to provide perfusion to distal organs during an

endovascular procedure, as somehow negating the plain language of the claims which say that the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded in those embodiments which are claimed. In the claimed configuration, blood is supplied through lumen 33 of the guiding catheter 30 from the proximal end of the catheter. (See paragraph [0034].) As illustrated in Figs. 1B, 2A-C, 3A-C, and 4A-C, the only entry port for lumen 33 is at the proximal end of the catheter 30. Appellant is aware on no requirement that the claims presented in a patent application must encompass every embodiment disclosed in the specification.

In the Advisory Action, the Examiner states:

> "Clearly Applicant must regard these features to be compatible with one another or these features would not be claimed together."

Appellant responds that the features in question are <u>not</u> claimed together. Port 70 of the embodiment of Fig. 5, if operated in the manner taught by Patel, would not be encompassed by either claim 53 or claim 68 for the simple reason that in that mode of operation the system would not be configured to stop flow in the manner recited in the claims. Other modes of operation would create differential pressures which would prevent port 70 from acting as an infusion port.

In the third section of the Advisory Action, the Examiner turns to the issue of whether the combination of Gray and Patel may reasonably be said to render obvious "a self-expanding stent coupled to the inner catheter shaft". Patel does not appear to teach a stent. Gray does appear to disclose a stent; however that stent is not self-expanding and is not retained in a collapsed condition by a retaining sleeve as acknowledged by the Examiner in the Final Office Action. The inner catheter of Gray appears only to provide the guidewire and filter, but does not appear at any time to have a stent, self-expanding or otherwise, associated therewith. Rather than addressing these deficiencies, the Advisory Action states: "Examiner sees no reason why this modification would not have been possible or would prevent the intended function of the Gray device. This assertion does not provide a motivation to combine the references and such a modification would impermissibly alter the operating principle of Gray which employs a thin catheter (20) which advances over a trackable path determined by a catheter guidewire. The lack of a

negative indication does not suffice to provide motivation. The catheter of Gray includes a balloon or stent mounted about the outer catheter (20). There is no third catheter which would appear capable of providing a retaining sleeve for a self-expanding stent. Patel provides no catheter which would be located to act as a delivery sheath for a self-expanding stent.

As may be seen in Fig. 2 of Patel, were a self-expanding stent to be delivered between guide catheter 11 and dilating catheter 29 as suggested by the Examiner's combination of the references in the Final Office Action, the stent would appear to deploy upon ejection within the ostium rather than at the stenotic lesion 31 within the coronary artery thereby rendering the device of Gray unsatisfactory for its intended purpose of delivering a stent to relieve a stenosis. The Examiner merely "maintains the position that this modification would have been obvious" without providing a motivation for the modification or even providing all elements of the claims which would be necessary to accomplish the modification.

For at least the above reasons, Gray in view of Patel does not teach all the claim limitations, as is required to establish a *prima facie* case of obviousness and the Examiner does not appear to have considered all words of the claims in rejecting independent claims 53 and 68.

> "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03).

Accordingly, Appellant respectfully requests that the rejection of independent claims 53 and 68 be overruled.

2. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious.

Claims 54-58, 60-65, and 69-71, which depend from independent claims 53 and 68 respectively, also are believed to be nonobvious and Appellant respectfully requests that the rejections be overruled.

D. CLAIMS 59, 66, 67, AND 78-80 ARE PATENTABLE UNDER 35 U.S.C. §103(a) OVER GRAY ET AL., WO 99/22673, IN VIEW OF PATEL, U.S. PATENT NO. 4,832,028, AS APPLIED TO CLAIMS 53 AND 56, AND FURTHER IN VIEW OF DUBRUL, U.S. PATENT NO. 6,258,115.

Initially, Appellant notes that claims 79 and 80 do not depend from either claim 53 or 56, but rather depend from nonobvious independent claim 68 and also are nonobvious. Appellant respectfully requests that the rejections of dependent claims 79 and 80 be overruled. In the alternative, the arguments below may be applied to Gray in view of Patel and Dubrul as applied to nonobvious independent claim 68.

Turning to the rejections of claims 59, 66, 67, and 78, Appellant notes that independent claim 53, as well as claim 56 which depends therefrom, is nonobvious over Gray in view of Patel as discussed above. The Examiner has asserted that "Dubrul teaches that it is known for self expanding stents to be thermally activated. (Column 9, lines 59-60)". Instead, the broader passage, column 9, lines 56-60 states:

> "Once in place, the multi-porous stent is deployed by expanding a balloon (not shown) thereunder to force the stent wall to expand within the vessel and be in correct orientation to the bifurcated tributary or side branch. Alternatively the stent 30 could be enlarged using thermal energy."

Thus, in context, it will be seen that the cited thermally expanded stent of Dubrul is a replacement for the balloon expanded stent of Dubrul and is not self-expanding, but rather is expanded by the action of an unspecified external agent which warms it. Further, the provision of a self-expanding stent by Dubrul would not appear to overcome the various deficiencies of Gray in view of Patel as applied to nonobvious independent claim 53 as discussed above.

Claims 59, 66, 67, and 78, which depend from nonobvious independent claim 53, also are nonobvious and Appellant respectfully requests that the rejections be overruled.

E. CONCLUSION.

For the reasons stated above, claim 63 was improperly rejected under 35 U.S.C. 112, first paragraph; the rejection of claim 78 under 35 U.S.C. 112, second paragraph is

moot in view of the amendment of that claim; claims 53-58, 60-65, and 68-71 are nonobvious over Gray in view of Patel; claims 59, 66, 67, and 78 are nonobvious over Gray in view of Patel and Dubrul; claims 79 and 80 appear to have been improperly rejected; claim 81 is not present in the pending claims; and the Examiner's rejections of claims 53-71 and 78-80 under 35 U.S.C § 103 should be overruled.

Respectfully submitted,

Date: July 14, 2010

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VIII. CLAIMS APPENDIX

1-52. (Cancelled)

53. A medical device for use in a body lumen, the device comprising:

a first catheter shaft having a proximal end region, a distal end region, and a fluid lumen connecting the proximal end region and the distal end region;

a second catheter shaft slidably disposed within the first catheter shaft;

a guidewire slidably disposed in a lumen of the second catheter shaft;

a filter coupled to the guidewire;

a balloon coupled to the distal end region of the first catheter shaft;

a stent disposed adjacent the second catheter shaft,

wherein the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded;

wherein the stent is self-expanding and configured to be deployed from a position between the distal end of the first catheter shaft and the filter; and

wherein the first catheter shaft defines a perfusion lumen configured for the passage of perfusing fluid supplied at the proximal end region therethrough so as to flush embolic debris into the filter.

54. The medical device of claim 53, wherein the second catheter shaft comprises a distal balloon and the stent is disposed about the distal balloon.

55. The medical device of claim 53, wherein the stent is disposed on the second catheter shaft.

56. The medical device of claim 55, wherein the stent is configured to shift between a first generally collapsed configuration and a second generally expanded configuration, and wherein the stent is self-biased to be in the second configuration.

57. The medical device of claim 56, wherein the stent is retained in the first configuration on the second catheter shaft by a retaining sleeve.

58. The medical device of claim 56, wherein the stent is retained in the first configuration on the second catheter shaft by the first catheter shaft.

59. The medical device of claim 56, wherein the self-biased stent is thermally activated.

60. The medical device of claim 53, wherein the device includes a perfusing fluid.

61. The medical device of claim 60, wherein the perfusing fluid is blood.

62. The medical device of claim 60, wherein the perfusing fluid is oxygenated.

63. The medical device of claim 53, wherein the first catheter shaft includes an infusion port within the proximal end region and proximal the balloon.

64. The medical device of claim 63, wherein the infusion port is configured to introduce blood into the perfusion lumen.

65. The medical device of claim 60, wherein the perfusion lumen is configured to direct the perfusing fluid at an inner surface of the body lumen.

66. The medical device of claim 53, wherein the device includes an aspiration catheter configured to remove embolic debris from the filter while the filter is percutaneously disposed in the body lumen.

67. The medical device of claim 66, wherein the aspiration catheter in configured to be slidably disposed in the first catheter shaft.

68. A medical device for use in a body lumen, the device comprising:

an outer catheter shaft having a proximal end and a distal end;

an inner catheter shaft slidably disposed in the outer catheter shaft, said inner catheter shaft having a proximal end and a distal end;

an elongate guidewire slidably disposed in the inner catheter shaft;

a filter coupled to the guidewire;

a balloon coupled to the outer catheter shaft; and

a self-expanding stent coupled to the inner catheter shaft,

wherein the balloon and the outer catheter shaft are configured to stop fluid from outside the outer catheter shaft proximal to the balloon from flowing distally past the balloon when the balloon is expanded; and

wherein at least one of the inner or outer catheter shafts define a perfusion lumen therein that is configured for perfusing fluid therethrough from an infusion port proximate the proximal end of the shaft so as to flush embolic debris into the filter.

69. The medical device of claim 68, wherein the stent is configured to shift between a first generally collapsed configuration and a second generally expanded configuration, and wherein the stent is biased to be in the second configuration.

70. The medical device of claim 69, wherein the stent is retained in the first configuration on the inner catheter shaft by a retaining sleeve.

71. The medical device of claim 69, wherein the stent is retained in the first configuration on the inner catheter shaft by the outer catheter shaft.

72. A method for flushing embolic debris into a filter, comprising the steps of:

providing a catheter system, the system including an outer catheter shaft, an inner catheter shaft slidably disposed in the outer catheter shaft, a distal flushing port, a balloon coupled to the outer catheter shaft, and a stent coupled to the inner catheter shaft;

providing an aspiration catheter configured for slidable insertion in the outer catheter shaft;

providing a guidewire having an expandable filter coupled thereto;

inserting the guidewire into a blood vessel;

advancing the guidewire to a position where the expandable filter is disposed distally beyond a region of interest;

expanding the filter;

advancing the catheter system over the guidewire to a position where the balloon is disposed proximally of the region of interest;

expanding the balloon;

removing the inner catheter shaft from the outer catheter shaft;

flushing the embolic debris towards the expandable filter through the flushing port of the catheter system, whereby the filter collects the embolic debris;

slidably inserting the aspiration catheter in the outer catheter shaft;

percutaneously removing embolic debris material from the filter using the aspiration catheter; and

removing the filter containing embolic debris material from the blood vessel.

73. The method of claim 72, wherein the distal flushing port of the catheter system is defined by a distal end of the outer catheter shaft, and wherein the step of flushing the embolic debris towards the expandable filter through the flushing port of the catheter system includes flushing the embolic debris towards the expandable filter through the distal end of the outer catheter shaft.

74. The method of claim 72, further comprising the step of deploying the stent.

75. The method of claim 74, wherein the stent is held in an undeployed configuration by a sleeve disposed on at least a portion of the stent, and wherein the step of deploying the stent includes removing the sleeve from the stent.

76. The method of claim 73, including providing a perfusion fluid and further comprising the step of introducing a perfusion fluid into the outer catheter shaft.

77. The method of claim 76, including providing an infusion port proximal the balloon and further comprising the step of introducing the perfusion fluid into the outer catheter shaft through the infusion port.

78. The medical device of claim 53, further comprising an aspiration catheter configured for slidable insertion in the ~~outer~~ first catheter shaft.

79. The medical device of claim 68, further comprising an aspiration catheter configured for slidable insertion in the outer catheter shaft.

80. The medical device of claim 68, further comprising an aspiration catheter configured for slidable insertion in the inner catheter shaft.

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

None.